US ERA ARCHIVE DOCUMENT

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CASWELL#315

DATE: April 23, 1979

SUBJECT: Section 18 emergency specific exemption for the use of 2,4-Damine on millet for the control of susceptible annual and perennial broadleaf weeds.

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TO: Hoyt Jamerson
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Emergency Response Section/RD

THRU: Dr. Adrian Gross, Chief
Toxicology Branch (TS-769) Milliam M. Butter for M. adecan Furst

The State of South Dakota has requested an emergency specific exemption for the use of 2,4-Damine on millet for the control of susceptible annual and perennial broadleaf weeds.

The product proposed for use is 2-4-Damine - 17,500 pounds total actual active ingredient.

Rate of application is 0.5 lbs. a.i. per acre.

The inert ingredients have been cleared. Treatment will consist of one application within the period of May 1 through July 1 to approximately 35,000 acres.

The Toxicology Branch concluded in their memo of June 28, 1977 (Toxicology Branch to H. Jamerson) that the hazard from granting this Section 18 exemption is very low or mil, for both human and domestic animals.

It is also stated that residues of nitrosamine would be <1.0 ppb <u>if any</u>. This level of nitrosamine is toxicologically insignificant.

Various tolerances have been established under 180.142 on grasses and marocotyledonous crop plants at the 0.5 and 1.0 ppm level.

An additional exposure of humans from this use is not expected and no direct adverse effects are expected to man or animals.

No tolerances have been established for any product for millet.

A hazard evaluation was previously performed on the use of 2,4-D on millet (see memos of Oct. 11, 1977, R. Engler and R. Coberly, PP#7E1980) and it was concluded that the risk if any for humans and domestic animals is negligible.

The Theoretical Maximum Residue Contribution (TMRC) is 0.903 mg/day (computer calculation); that is only about 12% of the ADI.

The toxicity submitted in support of prior petitions are as follows:

Acute Rat Oral LD50

2,4-D 300-400 mg/kg

2,4-D sodium salt 610-1060 mg/kg

2,4-D isopropyl ester 570-869 mg/kg

2,4-D mixed butyl ester 320-950 mg/kg

2,4-D mono, bi, Tripropylene glycol butyl ester eshar 510-640 mg/kg

2,4-D butyl ester technical males - 830 mg/kg females - 434 mg/kg

22 Week Cattle Feeding (PP272 &444) (12-5-63) NEL = 50 mg/kg
32 Week Rat Feeding (Dep of Pharmacology minimal changes at 1,000 ppm
113 Day Rat Feeding (PP#162(5-2-58) NEL = 300 ppm

90 Day Dog Feeding (PP#162)(5-2-58) NEL = 400 ppm

Chronic Dog Feeding (PP#272 & 414) (12-5-63) NEL = 500 ppm

Rat Reproduction Study (PP#459) (3-11-66) NEL = 500 ppm

2-Year Dog Feeding (PP#8F0670) (3-22-68) NEL = 500 ppm

2-Year Rat Feeding (PP#8F0670) (3-22-68) NEL = 1250 ppm

Rat Teratology No Terata at 25 mg/kg
Hamster Teratology No Terata at 40 mg/kg
Teratology on 2,7-dichloro dibenzo dioxin (rat & hamster) No Terata at 2 mg/kg
Carcinogenicity screen (mice) Bionetics Research No carcinogenicity

2,4-D is an RPAR Chemical.

Toxicology Branch, however, has concluded that the rat oncogenicity study conducted at FDA demonstrate that 2,4-D has no oncogenic effect under the test conditions.

Existing toxicity data will support the requested emergency temporary exemption for use of 2,4-D on millet in South Dakota.

TOX/HED:th:RD Initial WWOODROW:4-12-79